

# Instructions for Use of Vaccine Information Materials (Vaccine Information Statements)

## Required Use

As required under the National Childhood Vaccine Injury Act (42 U.S.C. § 300aa-26), all health care providers in the United States who administer any vaccine containing diphtheria\*, tetanus\*, pertussis\*, measles\*, mumps\*, rubella\*, polio\*, hepatitis B<sup>§</sup>, *Haemophilus influenzae* type b (Hib)<sup>§</sup>, or varicella (chickenpox)<sup>§</sup> vaccine shall, prior to administration of *each dose* of the vaccine, provide a copy to keep of the relevant current edition vaccine information materials that have been produced by the Centers for Disease Control and Prevention (CDC):

- (a) to the parent or legal representative of any child to whom the provider intends to administer such vaccine, and
- (b) to any adult to whom the provider intends to administer such vaccine.

The materials shall be supplemented with visual presentations or oral explanations, as appropriate.

“Legal representative” is defined as a parent or other individual who is qualified under State law to consent to the immunization of a minor.

\* - effective 4/15/92

§ - effective 6/1/99

## Additional Recommended Use of Materials

Health care providers may also want to give parents copies of all vaccine information materials prior to the first visit for immunization, such as at the first well baby visit.

## Use of Revised Polio Vaccine Information Materials

Effective January 1, 2000, a health care provider prior to administering any polio vaccine (whether inactivated poliovirus vaccine (IPV) or oral poliovirus vaccine (OPV)) shall give the patient (or in the case of a child, the parent or legal representative) a copy of the vaccine information materials dated January 1, 2000, titled “Polio Vaccine: What You Need to Know” in place of the February 1, 1999 and February 6, 1997 versions of the polio materials. In addition, if the health care provider intends to administer OPV, such person shall also be given a copy of the OPV supplemental vaccine information materials dated January 1, 2000, titled “Oral Polio Vaccine: What You Need to Know.”

## Current Editions of Other Vaccine Information Materials

Diphtheria, Tetanus, Pertussis (DTP/DTaP/DT) Vaccine Information Materials, dated August 15, 1997

Tetanus, Diphtheria (Td) Vaccine Information Materials, dated June 10, 1994

Measles, Mumps, Rubella (MMR) Vaccine Information Materials, dated December 16, 1998

Hepatitis B Vaccine Information Materials, dated December 16, 1998

*Haemophilus influenzae* type b (Hib) Vaccine Information Materials, dated December 16, 1998

Varicella (chickenpox) Vaccine Information Materials, dated December 16, 1998

## Recordkeeping

Health care providers shall make a notation in each patient's permanent medical record at the time vaccine information materials are provided indicating (1) the edition date of the materials distributed and (2) the date these materials were provided.

This recordkeeping requirement supplements the requirement of 42 U.S.C. § 300aa-25 that all health care providers administering these vaccines must record in the patient's permanent medical record (or in a permanent office log) the name, address and title of the individual who administers the vaccine, the date of administration and the vaccine manufacturer and lot number of the vaccine used.

## Applicability of State Law

Health care providers should consult their legal counsel to determine additional State requirements pertaining to immunization. The Federal requirement to provide the vaccine information materials supplements any applicable State law.

## Availability of Copies

Single camera-ready copies of the vaccine information materials are available from State health departments. Copies are also available on the Centers for Disease Control and Prevention's website at: <http://www.cdc.gov/nip/publications/VIS/>. Copies are available in English and in other languages.

12/17/99

64 FR 70914

42 U.S.C. § 300aa-26

